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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Daniel J. Sullivan

Examiner in immediately preceding
parent case: W. Lewis

Serial No.: Unknown

Anticipated Group Art Unit: 3731

Filed: October 30, 2000

Docket No.: 1001.1413102

For: GUIDEWIRE WITH MULTIPLE RADIOPAQUE SECTIONS AND METHOD OF USE

TRANSMITTAL SHEET

BOX: PATENT APPLICATIONS
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

CERTIFICATE UNDER 37 C.F.R. 1.10: The undersigned hereby certifies that this paper or papers, as described herein, are being deposited in the United States Postal Service, "Express Mail Post Office to Addressee" having an Express Mail mailing label number of : EL593905328US, in an envelope address to: Assistant Commissioner for Patents, Washington, D.C., 20231 on this 30th day of October, 2000.

By Diane Wimperis
Diane Wimperis

We are transmitting herewith the attached:

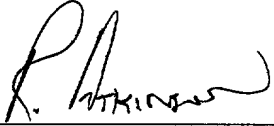
☐ Amendment

☐ No additional fee required

☐ The fee has been calculated as shown:

CLAIMS AS AMENDED							
	(3)	(4)	(5)	SMALL ENTITY		OTHER	
	REMAINING CLAIMS	HIGHEST PAID	EXTRA	RATE	ADD'L FEE	RATE	ADD'L FEE
TOTAL CLAIMS	-	=		X9=	\$	X18=	\$
INDEPEN- DENT CLAIMS	-	=		X39=	\$	X78=	\$
() FIRST MULTIPLE DEPENDENT CLAIM				+130=	\$	+260=	\$
TOTAL				\$		\$	

- [X] A check in the amount of \$ 710.00 is enclosed.
- [] Small entity status of this application under 37 C.F.R. 1.9 and 1.27 has been established by verified statement previously submitted.
- [X] Other: Continuation Application including 14 sheets of the Specification, 18 Claims, 1 Abstract sheet, 1 sheet of informal drawings, an Executed Declaration & Power of Attorney, Preliminary Amendment, Letter to Official Draftsman & 1 sheet of formal drawings.
- [X] Please charge any deficiencies or credit any overpayment in the enclosed fees to Deposit Account No. 50-0413.

By: 
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PRELIMINARY AMENDMENT

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By Diane Wimperis
Diane Wimperis

Dear Sir:

Please amend the above-captioned patent application as follows:

In the Title of the Invention

Beginning on page 1, line 1, please delete the entire title and insert the following text:

--GUIDEWIRE WITH MULTIPLE RADIOPAQUE SECTIONS AND METHOD OF
USE--

In the Claims

Please cancel claim 1 and insert new claims 11 - 30 as follows:

11. (New) An intravascular guidewire, comprising:
an elongate shaft having a proximal portion and a distal portion, the proximal portion comprising a solid wire which tapers distally, the distal portion comprising a radiopaque coil tip; and
a plurality of radiopaque markers disposed on the shaft proximal of the coil tip, the markers defining a plurality of longitudinal spaces therebetween.

12. (New) An intravascular guidewire as in claim 11, wherein the radiopaque markers comprise coils.

13. (New) An intravascular guidewire as in claim 11, wherein the longitudinal spaces are 1.5 cm.

14. (New) An intravascular guidewire as in claim 11, wherein the radiopaque markers are 1 mm wide.

15. (New) An intravascular guidewire, comprising:
an elongate shaft having a distal radiopaque tip; and
a plurality of radiopaque sections disposed on the shaft proximal of the tip, the radiopaque sections separated by a plurality of relatively non-radiopaque sections.

16. (New) An intravascular guidewire as in claim 15, wherein the elongate shaft includes a proximal portion comprising a wire, and a distal portion comprising the radiopaque tip.

17. (New) An intravascular guidewire as in claim 16, wherein the proximal portion of the shaft comprises a tapered wire.

18. (New) An intravascular guidewire as in claim 17, wherein the proximal portion of the shaft comprises a solid wire.

19. (New) An intravascular guidewire as in claim 15, wherein the radiopaque sections comprise coils.

20. (New) An intravascular guidewire as in claim 15, wherein the non-radiopaque sections comprise coils.

21. (New) An intravascular guidewire as in claim 15, wherein the non-radiopaque sections are 1.5 cm wide.

22. (New) An intravascular guidewire as in claim 15, wherein the radiopaque sections are 1 mm wide.

23. (New) An intravascular guidewire, comprising:
an elongate shaft having a distal radiopaque tip; and
a plurality of longitudinally spaced radiopaque markers disposed on the shaft proximal of the tip.

24. (New) An intravascular guidewire as in claim 23, wherein the markers define a plurality of longitudinal spaces therebetween.

25. (New) An intravascular guidewire as in claim 24, wherein the longitudinal spaces are 1.5 cm.

26. (New) An intravascular guidewire as in claim 24, wherein the radiopaque markers are 1 mm wide.

27. (New) An intravascular guidewire as in claim 23, wherein the elongate shaft includes a proximal portion comprising a wire, and a distal portion comprising the radiopaque tip.

28. (New) An intravascular guidewire as in claim 27, wherein the proximal portion of the shaft comprises a tapered wire.

29. (New) An intravascular guidewire as in claim 28, wherein the proximal portion of the shaft comprises a solid wire.

30. (New) An intravascular guidewire as in claim 29, wherein the radiopaque markers comprise coils.

REMARKS

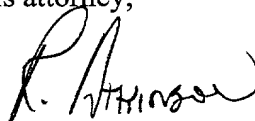
Applicants request that the preceding claim amendments be made of record and fully considered before the first office action on the merits. Any inquiry regarding this matter may be directed to the undersigned representative at (612) 677-9050.

Respectfully submitted,

DANIEL J. SULLIVAN

By his attorney,

Date: 10/30/00



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METHOD FOR PLACEMENT OF A BALLOON DILATATION
CATHETER ACROSS A STENOSIS AND APPARATUS THEREFOR

BACKGROUND OF THE INVENTION

5 1. Field of the Invention

The present invention relates to the field of angioplasty and in particular, to new and improved catheters for performing balloon angioplasty procedures on blood vessels.

10 2. Description of the Prior Art

Angioplasty has gained wide acceptance in recent years as an efficient and effective method for treating vascular diseases. Angioplasty is widely used in the treatment of stenosis within the coronary arteries, although it has been used for the treatment of stenosis in other areas of the vascular system.

15 The most widely used method of angioplasty makes use of a dilatation catheter which has an inflatable balloon member at a distal end and an inner lumen for acceptance of a guide wire (commonly called an "over-the-wire catheter"). The guide wire is typically about 175 cm in length, and is threaded through the vascular system by tracking radiopaque markers contained at a distal tip of the guide wire, which are monitored on an x-ray fluoroscope. Once the guide wire is positioned, the dilatation catheter is pushed along the guide wire until its balloon member is across the stenosis. The balloon member is subsequently inflated with liquid, exerting pressure radially and outwardly against the stenosis, causing the artery wall to stretch and re-establishing an acceptable blood flow through the artery.

20 An area of stenosis is normally transparent to x-ray fluoroscope viewing, but can be seen by a periodic injection of dye into the artery. This

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periodic injection allows a limited time fluoroscopic viewing of the restricted artery flow caused by the stenosis, allowing the guide wire to be positioned across the stenosis and into a distal artery, which provides support for the dilatation catheter. However, because dye injections cause surgical complications, physicians disfavor injecting additional dye into the artery in order to properly position the balloon member. On the other hand, physicians want to complete the operation as quickly as possible in order to minimize radiation exposure to the patient and staff. Thus, physicians do not want to spend a large amount of time trying to locate the stenosis. Therefore, there is a need for a method to properly mark a stenosis in order to timely position the balloon member without injecting additional dye.

In addition to properly positioning a first balloon member across the stenosis, some surgical procedures require the use of more than one dilatation catheter. For example, the balloon member of the first catheter might have a profile that is too large to fit into the stenosis. Using an extendable or exchange (300 cm in length) guide wire, a physician can exchange the first balloon member with a dilatation catheter having a second balloon member with a smaller profile, while attempting to maintain the guide wire in its position across the stenosis.

A dilatation catheter normally contains one or more markers to allow its balloon member to be located on a fluoroscope. To position the balloon

member without the use of additional dye, a method must be used whereby the stenosis can be pinpointed while the stenosis is temporarily displayed. One method is to use a grease pen to mark the location of the stenosis on the screen of the fluoroscope. Another method is to take a picture of the fluoroscope screen while the stenosis can be seen and then use the picture to later position the balloon member across the stenosis.

As can be readily appreciated, these methods of positioning a balloon member are generally time consuming and relatively inaccurate. Also, they require the patient to remain perfectly still in order to have the location marked on the screen correspond to the actual location of the stenosis. Keeping the patient still is especially difficult when a second dilatation catheter is needed to perform the procedure because of the additional time required to complete the catheter exchange on the guide wire. Therefore, there is a need for an accurate method of positioning a balloon member of an over-the-wire dilatation catheter across a stenosis in a timely fashion and without injecting additional dye to locate the stenosis.

SUMMARY OF THE INVENTION

Unlike previous balloon dilatation catheter systems which lack an accurate method and apparatus for marking the location of a stenosis to allow proper placement of a balloon member, the present invention offers the advantage of providing an apparatus and

method that allows the stenosis to be pinpointed with respect to a radiopaque marker on a distal portion of a guide wire. Once the location of the stenosis has been established relative to a radiopaque marker carried by the guide wire, the balloon member is placed across the stenosis by aligning the balloon member with respect to the radiopaque marker on the guide wire.

The present invention is an improved apparatus for use in combination with an over-the-wire balloon catheter having a radiopaque marker thereon at a known distance from a distal end of the catheter. An elongated flexible guide wire is provided, and the guide wire has a plurality of radiopaque markers on a distal portion thereof. Adjacent markers on the guide wire are longitudinally spaced by a distance equal to the known distance between a distal end of the catheter and its radiopaque marker.

In a preferred embodiment, the guide wire has a proximal solid wire portion and a distal coil spring portion. A distal radiopaque tip of 1.5 cm is provided on the guide wire, and the rest of the markers on the guide wire are spaced apart 1.5 cm and are each 1 mm in width. The length of the guide wire is preferably 175 cm.

The inventive method of positioning a balloon catheter relative to an artery stenosis begins by advancing the guide wire through the artery and across the stenosis such that a radiopaque marker on the guide wire pinpoints the location of the stenosis.

5 The balloon catheter is subsequently advanced to the
pinpointed location by aligning a radiopaque marker of
the balloon member with the radiopaque marker on the
guide wire corresponding to the location of the
stenosis. Because this location is pinpointed rela-
tive to the radiopaque marker on the guide wire,
additional dye is not needed to assure correct balloon
member placement. The balloon member is subsequently
inflated, causing the artery wall to stretch and re-
establishing an acceptable blood flow through the
artery.

10 To effect an exchange of balloon catheters
on the guide wire, the guide wire position is
maintained relative to the stenosis while the balloon
catheter (uninflated) is withdrawn proximally off of
the guide wire. A second balloon catheter bearing a
radiopaque marker is then advanced distally over the
guide wire until the marker on the catheter is aligned
with the marker of the guide wire which defines the
location of the stenosis. This second balloon is then
inflated to dilate the stenosis.

BRIEF DESCRIPTION OF THE DRAWINGS

15 FIG. 1 is a perspective view of an over-the-
wire dilatation catheter system in accordance with the
present invention.

20 FIG. 2 is an enlarged sectional view of a
distal portion of a guide wire and an over-the-wire
balloon dilatation catheter combination of the present
invention.

25 FIG. 3 is a sectional view as taken on line

3--3 of FIG. 2.

FIG. 4 is a sectional view as taken on line 4--4 of FIG. 2.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

5 Catheter 10, as shown in FIGS. 1-4, is an over-the-wire balloon dilatation catheter which includes a manifold 12, a shaft 14, a balloon member 16 and a guide wire 18.

10 Manifold 12, defining a proximal portion of catheter 10, provides a means for introducing the guide wire 18 and inflation fluid for the balloon member 16 into the shaft 14. A thumb screw 20 is threadably mounted on a proximal end of manifold 12 for use in fixing the position of guide wire 18
15 relative to the manifold 12, shaft 14 and balloon member 16.

The shaft 14 has an inner tube 22 (see FIG. 2), which is preferably formed from a plastic material such as polyimide, and is attached to the manifold 12
20 to extend distally therefrom and define a guide wire lumen 24 for the guide wire 18. An inner surface of the inner tube 22 is coated with a lubricous material, such as polytetrafluoroethylene, to facilitate movement of the guide wire 18 therethrough.

25 The manifold 12 has a dye injection port 26 between the thumb screw 20 and the proximal end of the inner tube 22. The dye injection port 26 is in fluid communication with the guide wire lumen 24, and is adapted for connection to an inflation device (not
30 shown) to provide fluid (e.g., radiopaque dye) under

pressure to the guide wire lumen 24.

5 The shaft 14 also has an outer tube 28,
attached to the manifold 12, which extends distally
therefrom around the inner tube 22. An annular
balloon inflation lumen 30 is thus defined between the
10 outer tube 28 and the inner tube 22. The manifold 12
has a balloon inflation port 32 which is in fluid
communication with the inflation lumen 30 and is
adapted for connection to an inflation device (not
shown) to provide fluid under pressure to the balloon
member 16 via the inflation lumen 30.

15 The outer tube 28 is an elongated flexible
elastic tube, preferably formed of polyimide. An
outer surface of the outer tube 28 has a lubricous
coating, such as polytetrafluoroethylene, which
provides a slippery surface to aid in inserting and
removing the catheter 10 into a guide catheter and
into a patient's vascular system. At a distal end 34,
20 outer tube 28 has a section of reduced diameter to
which a proximal or waist segment 36 of balloon member
16 is attached, preferably by an adhesive seal such as
epoxy.

25 Balloon member 16, which is preferably
formed from a polymer material such as polyolefin, has
the proximal or waist segment 36, a distensible
balloon segment 38 and a small diameter distal segment
40. Distal segment 40 of the balloon member 16 is
bounded to a distal end 42 of the inner tube 22, also
preferably by an adhesive seal such as epoxy. A
30 radiopaque balloon marker 43 is positioned about the

inner tube 22 near a longitudinal center of the balloon member 16 at a distance D from a distal end of the catheter 10.

5 Guide wire 18 has a proximal solid wire portion 44 which is preferably formed of a high strength steel or other high strength alloy. The solid wire portion 44 has a tapered distal end 46 which is received within and bonded to a proximal end 47 of a coil spring member 48, preferably by a braze bond. Spring member 48 defines a distal portion of the guide wire 18, and is formed from a multiplicity of alternating groups of radiopaque 50 and non-radiopaque 52 spring coils of a high strength steel or other high strength alloy.

10 Radiopaque markers 56 for the guide wire 18 are formed by sandwiching one or more radiopaque spring coils 50 between nonradiopaque spring coils 52. A radiopaque tip 58 is formed at a distal end of spring member 48 by a plurality of radiopaque spring coils 50. Proximally from the tip 58, adjacent radiopaque markers 56 are longitudinally spaced by the same distance D as is between the distal end of the catheter 10 and its balloon marker 43. The width of the radiopaque markers 56 will depend upon the number of radiopaque spring coils 50 used to form each marker.

15 In a preferred embodiment, the spring member 48 is 25 cm in length. The distance D between the distal end of catheter 10 and the balloon marker 43 is 1.5 cm. Thus, the radiopaque markers 56 are also

separated by 1.5 cm (distance D), with the radiopaque marker 56 closest to the radiopaque tip 58 being 1.5 cm from its proximal end. The width of each radiopaque marker 56 is preferably 1 mm. The total length of the guide wire is 175 cm.

The basic angioplasty procedure consists of inserting an introducer sheath, or short plastic tube, into a patient's thigh which provides an opening to the femoral artery. A guide catheter (not shown) is then advanced through the vascular system and into a position at the ostium of either the left or right coronary artery. The guide catheter is a hollow tube which serves as a channel from outside the patient's body through which catheter 10 can be advanced to the ostium of a coronary artery.

Prior to inserting the catheter 10 into the artery, the balloon member 16 is positioned on the guide wire 18 adjacent its distal radiopaque tip 58. Once in position, the thumbscrew 20 is tightened to fix the balloon member 16 position relative to the guide wire 18. The balloon member 16 and guide wire 18 assembly is then advanced to the ostium of the coronary artery. Using an inflation device which is connected to the dye injection port 26 or the guide catheter, a radiopaque dye is periodically injected into the artery to allow viewing of a stenosis on a fluoroscope. The thumbscrew 20 is loosened to allow the guide wire 18 to be advanced distally across the stenosis while it can be viewed on the fluoroscope. Of course, the guide wire 18 is also viewable on the

fluoroscope. The balloon member 16 remains at the ostium of the coronary artery until the guide wire 18 is advanced to a point beyond the stenosis to provide stability to the catheter 10.

5 Once the guide wire 18 is properly advanced beyond the stenosis, a physician records the position of the stenosis relative to one of the radiopaque markers 56 on the guide wire 18. This recording provides a reference point for the stenosis and thus
10 the periodic injection of dye (which had been necessary to locate the stenosis) can be ceased. The guide wire 18 is then held as still as possible across the stenosis while the balloon member 16 is advanced distally over the guide wire 18. This is done by
15 manually grasping a proximal end of the guide wire 18 outside of the body. The balloon member 16 is advanced until its radiopaque marker 43 is aligned with the stenosis reference marker 56 of the guide wire 18. After the balloon member 16 is properly
20 positioned with respect to the radiopaque marker 56, the thumbscrew 20 on the manifold 12 is tightened to prevent movement of the balloon member 16 relative to the guide wire 18.

25 The balloon member 16 is subsequently inflated via the inflation lumen 30 so that the distensible balloon segment 38 (shown inflated) expands, exerting pressure radially and outwardly against the stenosis and causing the artery wall to stretch. Once the dilation procedure is completed,
30 the balloon member 16 is deflated and removed, re-

establishing an acceptable blood flow through the artery.

5 The radiopaque markers 56 of the guide wire 18 allow the proper placement of balloon 16 across the stenosis without the need for additional continuous or even periodic injections of dye. This is advantageous to the patient because surgical complications arise from the dye injections. Also, this method allows the operation to be performed quickly and efficiently, thereby minimizing radiation exposure to the patient and staff.

10 The inventive method is also useful in angioplasty procedures which require the use of more than one balloon dilatation catheter. For instance, 15 balloon member 16 of catheter 10 is sometimes too large to fit through the stenosis, or conversely, is so small that upon inflation of the balloon member 16, the stenosis is not sufficiently dilated. In these situations, balloon member 16 must be exchanged for a 20 balloon member of a different size. If the balloon member 16 was too large to fit through the stenosis, a balloon member with a smaller profile must be used. On the other hand, if upon inflation of the balloon member 16 the stenosis was not sufficiently dilated, 25 a balloon member with a larger inflated profile must be inserted to allow a widening of the dilated coronary artery.

30 In order to exchange balloon member 16 for a different balloon member, the guide wire 18 must be held outside the body (near the femoral artery) so

that its position does not move relative to the stenosis. As the guide wire 18 is held in position, the thumbscrew 20 is loosened, allowing the balloon member 16 to be moved proximally along the guide wire 18 and out of the patient's body. The balloon member 16 is continually withdrawn until it is removed from the body and is completely removed from the proximal end of the guide wire 18.

A second dilatation catheter containing a correctly sized balloon member is then placed on the proximal end of the guide wire 18 and moved distally over the guide wire 18. The second dilatation catheter also has a radiopaque marker at a known point of its balloon member (preferably at its midpoint), and the second catheter is advanced along the guide wire 18 until the catheter's marker is aligned as desired with the recorded radiopaque marker 56 on the guide wire 18. The position of the balloon member of the second catheter is then fixed by again tightening the thumbscrew 22. During the entire exchange process, the physician attempts to hold the guide wire 18 steady and in place across the stenosis. If desired, dye may be injected to verify the position of the guide wire 18 and its recorded radiopaque marker 56 or the balloon member once it has been advanced to the recorded marker 56. The second balloon member is then inflated with an inflation medium, applying pressure radially and outwardly to the artery to dilate the stenosis and re-establish an acceptable blood flow through the artery. Upon completion of the

angioplasty operation, the second dilatation catheter, guide wire 18, and guide catheter are removed from the patient's thigh.

By providing a guide wire with known spacings between radiopaque markers thereon, and a balloon dilatation catheter having a similar spacing known between its distal end and a radiopaque marker thereon, the positioning of the catheter balloon relative to the guide wire (which is positioned relative to the artery stenosis) is greatly facilitated. For example, if the fifth marker (from a distal end) on the guide wire is aligned across the narrowest point of the stenosis (as detected by fluoroscopy), then the central marker of the balloon is moved over that fifth marker to place the balloon in the most advantageous position for inflation. As can be appreciated, once a marker on the guide wire is identified as across the stenosis, no further dye injections are necessary to align the catheter balloon, except to possibly recheck the guide wire marker location or to verify that balloon inflation has indeed dilated the artery.

The use of guide wire marker spacings equal to the distance from the distal end of the catheter to its balloon midpoint further assure the physician of balloon position and alignment by providing three reference points as to where the balloon member will be located when it is positioned across the stenosis. The three reference points are the fifth marker which will indicate the location of the midpoint of the

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WHAT IS CLAIMED IS:

1. For use in combination with an over-the-wire balloon catheter having a reference radiopaque marker thereon at a known distance from a distal end of the catheter, the improvement which comprises:
an elongated flexible guide wire having a plurality of longitudinally spaced radiopaque markers on a distal portion thereof, with adjacent markers on the guide wire being longitudinally spaced by a distance equal to the known distance between the distal end of the catheter and its reference radiopaque marker.
2. The guide wire of claim 1 wherein a proximal portion of the guide wire is a solid wire.
3. The guide wire of claim 1 wherein the distal portion of the guide wire is defined by a coil spring.
4. The guide wire of claim 1 wherein the distal portion of the guide wire has a radiopaque distal tip 1.5 cm in length.
5. The guide wire of claim 4 wherein the distance between adjacent markers on the guide wire is 1.5 cm, a first marker located 1.5 cm from a proximal end of the distal tip.

6. The guide wire of claim 1 wherein the distance between adjacent markers is 1.5 cm.

7. The guide wire of claim 1 wherein the guide wire has a radiopaque tip marker, and wherein the width of each marker on the guide wire, other than the tip marker, is 1 mm.

8. The guide wire of claim 2, wherein the distal portion of the guide wire is 25 cm in length.

9. A method of positioning a balloon catheter in an artery by use of fluoroscopy, comprising the steps of:

advancing a guide wire having a plurality of radiopaque markers at spaced intervals adjacent its distal end to a desired position relative to a stenosis; and

advancing a balloon catheter carrying a radiopaque marker over the guide wire until the radiopaque marker of the balloon catheter is in a predetermined positional relationship to one of the radiopaque markers of the guide wire.

10. The method of claim 9, and further comprising the steps of:

maintaining the guide wire in position relative to the stenosis;

000001-999999

[illegible]

METHOD FOR PLACEMENT OF A BALLOON DILATATION
CATHETER ACROSS A STENOSIS AND APPARATUS THEREFOR

ABSTRACT OF THE DISCLOSURE

An over-the-wire balloon catheter has a radiopaque marker thereon at a known distance from a distal end of the catheter. An elongated flexible guide wire has a plurality of longitudinally spaced radiopaque markers on a distal portion thereof, with adjacent markers on the guide wire being longitudinally spaced by a distance equal to the known distance between the distal end of the catheter and its radiopaque marker. The guide wire is advanced through an artery until one of its markers is positioned at a desired location relative to a stenosis. Subsequently, the balloon catheter is advanced over the guide wire until the radiopaque marker of the catheter is in a predetermined position relationship to the radiopaque marker of the guide wire which has aligned on the stenosis. The cooperating radiopaque markers of the guide wire and catheter thus allow the balloon member of the catheter to be positioned relative to the stenosis in a timely fashion without the need to constantly inject fluoroscopic dye to view the stenosis.

G:\DAB\WAS\PATFILE\S347\12-87.APP

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EL593905889 US

in an envelope addressed to:

Assistant Commissioner for Patents
Washington, DC 20231

on this 30th day of October, 2000
Crompton, Seager & Tufts, LLC

By: Diane Wimperis

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Daniel J. Sullivan

Serial No.: Unknown

Examiner in immediately preceding
parent case: W. Lewis

Filed: October 30, 2000

Anticipated Group Art Unit: 3731

For: GUIDEWIRE WITH MULTIPLE RADIOPAQUE SECTIONS AND METHOD OF USE

Docket No.: 1001.1413102

LETTER TO OFFICIAL DRAFTSMAN

CERTIFICATE UNDER 37 C.F.R. 1.10: The undersigned hereby certifies that this paper or papers, as described herein, are being deposited in the United States Postal Service, "Express Mail Post Office to Addressee" having an Express Mail mailing label number of : EL593905889US an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C., 20231 on this 30th day of October, 2000.

By Diane Wimperis
Diane Wimperis

Dear Sir:

Please find attached hereto one (1) sheet(s) of formal drawings for filing in the above-identified application.

Respectfully submitted,

DANIEL J. SULLIVAN

By his attorney,

Date 10/30/00

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Robert E. Atkinson
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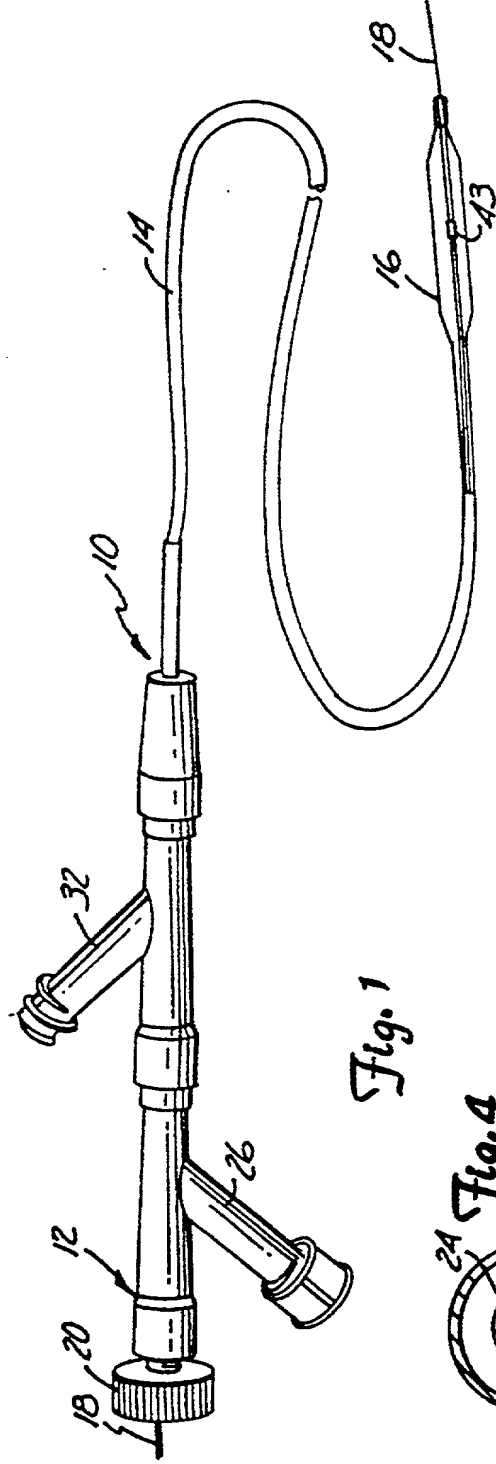


Fig. 1

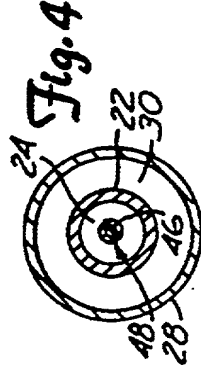


Fig. 4

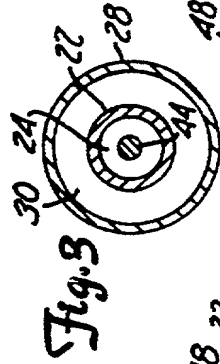


Fig. 3

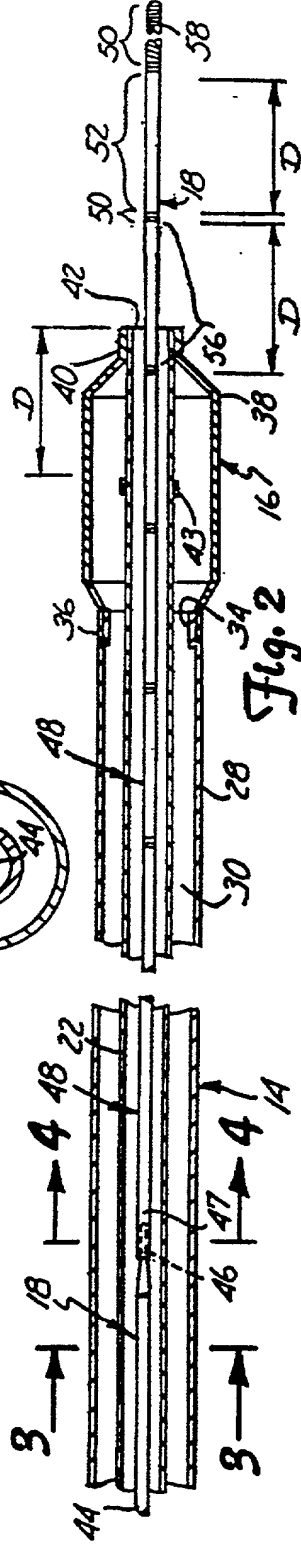


Fig. 2

As a below named inventor, I hereby declare that:

I believe I am the original, first and sole inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled METHOD FOR PLACEMENT OF A BALLOON DILATATION CATHETER ACROSS A STENOSIS AND METHOD THEREFOR the specification of which,

_____ was filed on _____
_____ and was amended on _____
_____ (if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, § 1.56(a). I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign applications for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Number	Country	Day/Month/Year Filed	Priority Claimed
_____	_____	_____	Yes _____ No _____
_____	_____	_____	Yes _____ No _____

I hereby claim the benefit under Title 35, United States Code § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

I hereby appoint the following attorneys and/or agents to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: Nickolas E. Westman, Reg. No. 20,147; David R. Fairbairn, Reg. No. 26,047; Wayne A. Sivertson, Reg. No. 25,645; Z. Peter Sawicki, Reg. No.

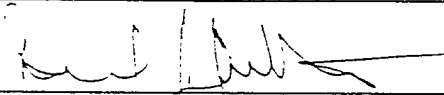
30,214; James L. Young, Reg. No. 30,514; Theodore F. Neils, Reg. No. 26,316; Norman P. Friederichs, Reg. No. 24,919; Charles J. Ungemach, Reg. No. 18,984; Joseph R. Kelly, Reg. No. 34,847; Jennifer F. Becker, Reg. No. 34,775; Judson K. Champlin, Reg. No. 34,797; Thomas A. Rendos, Reg. No. 33,349; Emery L. Tracy, Reg. No. 34,081; David D. Brush, Reg. No. 34,557; Robert M. Angus, Reg. No. 24,383; and Deirdre A. Megley, Reg. No. P-35,612.

Address all telephone calls to Wayne A. Sivertson at telephone number (612) 339-1863.

Address all correspondence to Wayne A. Sivertson, Suite 1500, 625 Fourth Avenue South, Minneapolis, Minnesota 55415.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Inventor:


(Signature)

Date:

10 - 28 - 92

Inventor: Daniel J. Sullivan
(Printed Name)

Residence: Plymouth, Minnesota

Citizenship: U.S.A.

P.O. Address: 3735 Rosewood Lane North, Plymouth, MN 55441

CONFIDENTIAL

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Daniel J. Sullivan

Serial No.: 08/673,674

Examiner: William Lewis

Filed: June 26, 2000

Group Art Unit: 3731

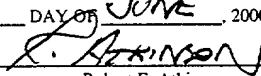
For: GUIDEWIRE WITH MULTIPLE RADIOPAQUE SECTIONS AND METHODS
OF USE

Docket No.: 1001.1413101

REVOCATION OF PRIOR POWERS OF ATTORNEY
AND POWER OF ATTORNEY

Assistant Commissioner
for Patents
Washington, D.C. 20231

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS
BEING DEPOSITED WITH THE UNITED STATES
POSTAL SERVICE AS FIRST CLASS MAIL IN AN
ENVELOPE ADDRESSED TO: ASSISTANT
COMMISSIONER FOR PATENTS, WASHINGTON, D.C.
20231.

29 DAY OF JUNE, 2000

Robert E. Atkinson

Dear Sir:

SciMed Life Systems, Inc., the owner of the entire right, title and interest in and to the above-identified patent/application, hereby revokes all previous powers of attorney and appoints the following attorneys and/or agents to prosecute the above-identified patent or application, including all continuations and divisionals thereof, and to transact all business in the U.S. Patent and Trademark Office connected therewith: David M. Crompton, Reg. No. 36,772; Glenn M. Seager, Reg. No. 36,926; Brian N. Tufte, Reg. No. 38,638; Craig F. Taylor, Reg. No. 40,199; Robert E. Atkinson, Reg. No. 36,433; Allen W. Groenke, Reg. No. 42,608; Thomas L. McMasters, Reg. No. 45,593; Luke Dohmen, Reg. No. 36,783; Peter J. Gafner, Reg. No. 36,517; Robert M. Rauker, Reg. No. 40,782; Todd P. Messal, Reg. No. 42,883; Albert K. Kau, Reg. No. 40,672; David L. Cavanaugh, Reg. No. 36,476; and William J. Shaw, Reg. No. 43,111.

Pursuant to 37 C.F.R. §3.73(b), SciMed Life Systems, Inc., a corporation certifies that it is the assignee of the entire right, title and interest in the patent application identified above by virtue of an assignment, recorded on September 10, 1992, at Reel 6318, Frame 0866.

The undersigned (whose title is supplied below) is empowered to act on behalf of the assignee by virtue of the attached Limited Authorization to Act on Behalf of Assignee Regarding Certain Patent Matters.

Address all telephone calls to Robert E. Atkinson at telephone number (612) 677-9050.

Address all correspondence to Robert E. Atkinson, CROMPTON, SEAGER & TUFTE, LLC, 331 Second Avenue South, Suite 895, Minneapolis, Minnesota 55401-2246.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

SciMed Life Systems, Inc.

Date: June 21, 2000 By: Peter J. Seager